k122858

510(k) Summary

ELITech Clinical Systems AMYLASE SL

OCT 3 2012

1.	Date:	September 14, 2012
2.	Submitter:	ELITech Clinical Systems SEPPIM S.A.S Zone Industrielle 61500 SEES FRANCE
3.	Contact Person:	Debra K. Hutson Director, QARA, North America 21720 23rd Dr SE, Suite 150 Bothell, WA 98021 Phone: 425-482-5174 Fax: 425-482-5550 Email: d.hutson@elitechgroup.com
4.	Device Description: Classification	ELITech Clinical Systems AMYLASE SL Class II JFJ Clinical Chemistry 21 CFR 862.1070
	Device Description: Classification	ELITech Clinical Systems ELICAL 2 Class II JIX Clinical Chemistry 21 CFR 862.1150
	Device Description: Classification	ELITech Clinical Systems ELITROL I and ELITROL II Class I, reserved JJY Clinical Chemistry
5.	Predicate Device:	k063744 Roche Diagnostics AMYL2 (α-Amylase EPS ver.) k033501 Roche Diagnostics Calibrator for Automated Systems (C.f.a.s.) k041227 Roche Diagnostics Precinorm and Precipath
6.	Intended Use	
	Reagents:	ELITech Clinical Systems AMYLASE SL is intended for the quantitative *in vitro* determination of amylase in human serum and plasma on ELITech Clinical Systems Selectra analyzers. It is not intended for use in Point of Care settings. Measurements of amylase are used primarily for the diagnosis and treatment of pancreatitis (inflammation of the pancreas).
	Calibrators:	ELITech Clinical Systems ELICAL 2 is a multi-parametric

calibrator for *in vitro* diagnostic use in the calibration of quantitative ELITech Clinical Systems methods on ELITech Clinical Systems Selectra analyzers.

Controls: ELITech Clinical Systems ELITROL I and ELITROL II are multi-parametric control sera for *in vitro* diagnostic use in accuracy control of quantitative ELITech Clinical Systems methods on ELITech Clinical Systems Selectra analyzers.

Special conditions for use statement(s):
Prescription Use Only. It is not intended for use in Point of Care settings.

Special instrument requirements:
Performance was provided for the ELITech Clinical Systems Selectra ProM.

7. **Device Description**

ELITech Clinical Systems AMYLASE SL is available as kit only. It consists of one reagent R whose the composition is: MES buffer (pH 6.15), sodium chloride, calcium chloride, potassium thiocyanate, CNP-G3 (2-chloro-4-nitrophenyl-α-maltotrioside), sodium azide.

ELITech Clinical Systems ELICAL2 is a lyophilized calibrator based on human serum containing constituents to ensure optimal calibration. ELICAL 2 is prepared exclusively from the blood of donors tested individually and found to be negative for HbsAg and to the antibodies to HCV and HIV according to FDA-approved methods.

ELITech Clinical Systems ELITROL I and ELITROL II are two level quality control products consisting of a lyophilized human serum containing constituents at desired levels. ELITROL I and ELITROL II are prepared exclusively from the blood of donors tested individually and found to be negative for HbsAg and to antibodies to HCV and HIV according to FDA-approved methods.

8. **Substantial Equivalence Information -**
Assay

1. Predicate Device Name
   Roche Diagnostics AMYL2 (α-Amylase EPS ver.)
2. k063744
3. Comparison with predicate

Similarities

Parameter	**AMYLASE SL**	**Roche Diagnostics AMYL2 (α-Amylase EPS ver.)**
Intended Use	Intended for the quantitative *in vitro* determination of amylase in human serum and plasma on ELITech Clinical Systems Selectra analyzers. It is not intended for use in Point of Care settings.	*In vitro* test for the quantitative determination of amylase in human serum and plasma on the cobas c111 system.
Specimen Type	Serum, Plasma	Same
Assay Technology	Enzymatic method	Same
Calibration frequency	28 days	Same

Differences

Parameter	AMYLASE SL	Roche Diagnostics AMYL2 (α-Amylase EPS ver.)
Assay Range	Serum/plasma:20 – 1500 U/L	Serum/plasma: 3-1500 U/L
Instrument	Selectra ProM analyzer	cobas c111
Calibrator	Recommended calibration material (not included): ELITech Clinical Systems ELICAL 2	Recommended calibration material (not included): Roche Calibrator f.a.s.
Interference	**Triglycerides:** No significant interference up to 3000 mg/dL. **Unconjugated bilirubin:** No significant interference up to 30.0 mg/dL (513 µmol/L). **Conjugated bilirubin:** No significant interference up to 29.5 mg/dL (504 mol/L). **Ascorbic acid:** No significant interference up to 20.0 mg/dL. **Acetaminophen:** No significant interference up to 30.0 mg/dL. **Acetylsalicylic acid:** No significant interference up to 200.0 mg/dL.	**Hemoglobin:** No significant interference up to an H Index of 100 (approximate 100 mg/dL). **Lipemia (Intralipid):** No significant influence up to an L index of 1000. **Icterus:** No significant influence up to I Index of 15 (approximate conjugated and unconjugated bilirubin concentration of 15 mg/dL (257µmol/L)).
Reference Range	Serum/plasma: [1]< 31-107 U/L	Serum/plasma: 28-100 U/L

[1] Schumann, G., et al.. IFCC Primary Reference Procedures for the Measurement of Catalytic Activity Concentrations of Enzymes at 37°C, Clin Chem Lab Med, (2006), 44(9), 1146.

Control Sera

1. Predicate Device Name:
   Roche Diagnostics Precinorm U and Precipath U
2. k041227
3. Comparison with predicate

Similarities and Differences		
Item	Candidate Device (ELITech Clinical Systems ELITROL I and ELITROLII)	Predicate Roche Diagnostics Precinorm U and Precipath U (k041227)
Intended Use/Indications for Use	ELITech Clinical Systems ELITROL **I** and ELITROL **II** are multi-parametric control sera for *in vitro* diagnostic use in quality control of quantitative ELITech Clinical Systems methods on ELITech Clinical Systems Selectra Analyzers.	Precinorm U is for use in quality control by monitoring accuracy and precision for the quantitative methods as specified in the value sheets. Precipath U is for use in quality control by monitoring accuracy and precision for the quantitative methods as specified in the value sheets.
Format	Lyophilized human sera with constituents added as required to obtain defined component levels	Same
Levels	Two Levels (Level I and Level II)	Same
Stability	Lyophilized: Store at 2-8°C and protected from light until the expiry date. After Reconstitution: 12 hours between 15-25°C, 5 days between 2-8°C, 4 weeks between -25 and -15°C (when frozen once)	Same

Calibrator

1. Predicate Device Name:
   Roche Diagnostics Calibrator for Automated Systems (C.f.a.s)
2. k033501
3. Comparison with predicate

Similarities and Differences		
Item	Candidate Device (ELITech Clinical Systems ELICAL 2)	Predicate Roche Calibrator for Automated Systems (C.f.a.s.) k033501
Intended Use/Indications for Use	ELITech Clinical Systems ELICAL 2 is a multi-parametric calibrator for *in vitro* diagnostic use in the calibration of quantitative ELITech Clinical Systems methods on ELITech Clinical Systems Selectra analyzers.	Calibrator for automated systems (C.f.a.s.) is for use in the calibration of quantitative Roche methods on Roche clinical chemistry analyzers as specified in the value sheets.

Format	Lyophilized calibrator based on human serum with constituents added as requires to obtain desired component levels	Same
Level	Single Level	Same
Stability	Lyophilized: store at 2-8°C and protect from light until the expiry date. After reconstitution: 8 hours between 15-25°C, 2 days between 2-8°C, 4 weeks between -25 and -15°C (when frozen once)	Same

9. **Standard/Guidance Document Reference**

- Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline—Second Edition. CLSI (NCCLS) document EP5-A2, Vol 24, No. 25, August 2004.
- Protocols for Determination of Limits of Detection and Limits of Quantification; Approved Guideline. CLSI (NCCLS) document EP17-A, vol 24, No. 34, October 2004.
- Method Comparison and Bias estimation Using Patient Samples; Approved Guideline—Second Edition. CLSI (NCCLS) document EP9-A2-IR, Vol 30, No. 17, July 2010.
- Use of Symbols on Labels and in Labeling of In Vitro Diagnostic Devices Intended for Professional Use: Guidance for Industry and FDA Staff, November 2004.
- Interference Testing in Clinical Chemistry; Approved Guideline—Second Edition. CLSI (NCCLS) document EP07-A2, Vol 25, No. 27, November 2005.
- Evaluation of the Linearity of the Measurement of Quantitative Procedures: a Statistical Approach; Approved Guideline. CLSI (NCCLS) document EP6-A, Vol 23, No. 16, April 2003.

10. **Test Principle:**

Enzymatic Method.
Substrate CNP-G_3 is hydrolyzed by catalitic action of a-amylase to produce CNP (2-chloro-4-nitrophenol).

$$5\ \text{CNP-G}_3 \xrightarrow{\alpha\text{-amylase}} 3\text{CNP} + 2\text{CNP-G}_2 + 3\ \text{Maltotriose} + 2\ \text{Glucose}$$

CNP-G_2 = 2-Chloro-4-nitrophenyl-α-maltoside

The rate of increase in absorbance is measured at 405 nm and is directly proportional to the activity α-amylase in the sample.

11. **Performance Characteristics – Analytical Performance**

a. Precision/Reproducibility

The precision of the device was determined in accordance with Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline—Second Edition. CLSI (NCCLS) document EP5-A2, Vol 24, No. 25, August 2004.

Within-run and Total precision results were obtained by performing two runs per day, two measures per run, for 3 levels of samples on 2 instruments during twenty operating days according to CLSI EP5-A2 protocol. The results are presented in the table below:

Within-Run Precision

	n	Mean (U/L)	Within-run SD	Within-run CV%
Level 1	80	82	1.07	1.3
Level 2	80	204	1.81	0.9
Level 3	80	992	14.50	1.5

Total Precision

	n	Mean (U/L)	Total SD	Total CV%
Level 1	80	82	2.21	2.7
Level 2	80	204	4.40	2.2
Level 3	80	992	25.36	2.6

b. Linearity/assay reportable range

The linearity study of AMYLASE SL reagent was performed according to CLSI protocol EP6-A. From this study, a measuring range from 20 to 1500 U/L has been determined. Manual dilution 1 to 10 allows an upper linearity of AMYLASE SL reagent to 15000 U/L.

c. Traceability

For calibration, a multi-parametric calibrator named ELITech Clinical Systems ELICAL 2 (manufactured by SEPPIM under product code CALI-0580) must be used. Its value is traceable to the IFCC method.

d. Stability

Real-time stabilities:
On board stability for the ELITech Clinical Systems AMYLASE SL was established by real time studies on the ELITech Clinical Systems Selectra ProM. The on-board stability of the reagent is 28 days. The shelf-life of AMYLASE SL reagent has been followed in the real time for 24 months on 3 different batches.

Control material is purchased from a commercial vendor (previously cleared under k041227). The following is claimed for stability: Before reconstitution, the shelf-life of the ELITech Clinical Systems Elitrol I and Elitrol II is 24 months at 2-8°C. After reconstitution the stability is 12 hours when stored at 15-25°C, 5 days when stored at 2-8°C or 4 weeks (when frozen once) at -25° and -15° C.

Calibrator material is purchased from a commercial vendor (previously cleared under k033501). The following is claimed for stability: Before reconstitution, the shelf-life of ELITech Clinical Systems Elical 2 is stable 24 months at 2-8°C. After reconstitution the stability is 8 hours when stored at 15-25°C, 2 days at 2-8°C or 4 weeks (when frozen once) at -25°and -15°C. The labeling stated that the Elical 2 should be stored tightly capped and protected from light when not in use.

Value Assignment
Elitrol I and II are value assigned using multiple Vital Scientific Pro M analyzers. Each sample is tested in triplicate over several days. The target value of Level I and II are the median of the observed values range. After validation of the target value, a confidence range (high and low values) is then calculated.

Elical 2 is tested against predetermined values on multiple Vital Scientific Pro M using the AMYLASE SL reagent and 2 levels of quality control material. The mean analyte value is calculated and a target value is assigned.

e. Detection limit

Determined according to CLSI protocol EP17-A (Protocols for Determination of Limits of Detection and Limits of Quantification; Approved Guideline).

Limit of Detection (LoD) of AMYLASE SL obtained from 15 measurements of 4 samples with a low concentration of analyte (approximately 4 x LoB ~ 13 U/L) is 6 *U/L*.

Limit of Quantification (LoQ) of AMYLASE SL obtained from 15 measurements of 4 samples at nominal concentration 13 U/L is *13 U/L*.

f. Interference/analytical specificity

Interferences due to unconjugated bilirubin, conjugated bilirubin, triglycerides, hemoglobin, acetaminophen, ascorbic acid, acetylsalicylic acid were investigated following the recommended sample levels in CLSI EP7-A2 protocol (Interference Testing in Clinical Chemistry; Approved Guideline – Second Edition).
The results of testing interferences are the following:

- Concentration up to 30.0 mg/dL unconjugated bilirubin, 29.5 mg/dL unconjugated bilirubin, 3000 mg/dL triglycerides and 500 mg/dL hemoglobin do not show any significant interference for each substance.
- Likewise, concentrations up to 30 mg/dL acetaminophen, 20.0 mg/dL ascorbic acid and 200 mg/dL acetylsalicylic acid do not show any significant interference for each substance.

The following statement will also be included in the labeling:

Other compounds may interfere. Users should refer to the two following literature references:
-Young, D. S., Effects of preanalytical variables on clinical laboratory tests, 2nd Ed., AACC Press, (1997).
-Young, D. S., Effects of drugs on clinical laboratory tests, 4th Ed., AACC Press, (1995).
-Berth, M. & Delanghe, J. *Protein precipitation as a possible important pitfall in the clinical chemistry analysis of blood samples containing monoclonal immunoglobulins: 2*

case reports and a review of literature, Acta Clin Belg., (2004), **59**, 263.

12. **Performance Characteristics – Comparison Studies**

a. Method comparison

A correlation study was performed between AMYLASE SL reagent on a Selectra ProM analyzer and Roche Diagnostics AMYL2 (α-Amylase EPS ver.) reagent on a cobas c111 analyzer according to CLSI EP9-A2 protocol (Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline – Second edition).
This study was performed using 100 serum patient samples from 21 to 1439 U/L over a span of 5 days.
Regression analysis of the results yielded the following:

y = 0.976 x -1 U/L
r = 0.999
r^2 = 0.999
Standard error of the estimate Sy.x = 10 U/L.

b. Comparison study: Plasma comparison

48 paired plasma (in lithium heparin samples, ranging from 22 to 1491 U/L, were tested on Selectra ProM analyzer according to CLSI protocol EP9-A2 (Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline – Second edition).
Regression analysis of the results yielded the following:
y = 0.907 x + 1 U/L
r = 1.000
r^2 = 1.000
Standard error of the estimate Sy.x = 6 U/L.

c. Matrix comparison:

Matrix comparison studies were not performed. See serum and plasma method comparison data above (Section 12 a. & b.)
We claim that lithium heparin plasma is an acceptable anticoagulant.

d. Expected values/Reference Range

As indicated in the instructions for use for AMYLASE SL, each laboratory should establish and maintain its own reference values. The values given are used as guidelines only.

< 31-107 U/L

These values are from "Schumann, G., *et al.. IFCC Primary Reference Procedures for the Measurement of Catalytic Activity Concentrations of Enzymes at 37°C*, Clin Chem Lab Med, (2006), **44**(9), 1146."

d. Clinical Studies:

Not applicable

e. Clinical Cut-off:

Not applicable

13. **Conclusion**

The information on the principle and performance of our device that is contained in this premarket notification is complete and supports a decision that our device is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

10903 New Hampshire Avenue
Silver Spring, MD 20993

ELITech Group
EPOCH Biosciences
c/o Debra K. Hutson,
Director, QARA, North America
21720 23rd Dr SE, Suite 150
Bothell, WA 98021

OCT 3 2012

Re: k122858
Trade Name: ELITech Clinical Systems AMYLASE SL;
ELITech Clinical Systems ELICAL 2;
ELITech Clinical Systems ELITROL I and ELITROL II
Regulation Number: 21 CFR §862.1070
Regulation Name: Amylase test system.
Regulatory Class: Class II
Product Codes: JFJ, JIX and JJY
Dated: September 14, 2012
Received: September 18, 2012

Dear Ms. Hutson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Devices and Radiological Health at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH'S Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-576-. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/Medical Devices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance...

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800 638-2041 or (301) 796-5680 or at its Internet address http://www.fda/gov/MedicalDevices/ResourcesforYou/Industry/default.htm

Sincerely yours,

Courtney H. Lias, Ph.D
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostics and
Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): _ _k122858_____

Device Name: _____ ELITech Clinical Systems AMYLASE SL

Indications for Use:

ELITech Clinical Systems AMYLASE SL is intended for the quantitative *in vitro* determination of amylase in human serum and plasma on ELITech Clinical Systems Selectra analyzers.

It is not intended for use in Point of Care settings.

Measurements of amylase are used primarily for the diagnosis and treatment of pancreatitis (inflammation of the pancreas).

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Yung Chan

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K122858

Indications for Use Form

510(k) Number (if known): _k122858_

Device Name: ELITech Clinical Systems ELICAL 2

Indications for Use:

ELITech Clinical Systems ELICAL 2 is a multi-parametric calibrator for *in vitro* diagnostic use in the calibration of quantitative ELITech Clinical Systems on ELITech Clinical Systems Selectra analyzers.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Yung Chan

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K122858

Indications for Use Form

510(k) Number (if known): _ k122858_

Device Name: ELITech Clinical Systems ELITROL I
ELITech Clinical Systems ELITROL II

Indications for Use:

ELITech Clinical Systems ELITROL I & ELITROL II are multi-parametric control sera for *in vitro* diagnostic use in quality control of quantitative ELITech Clinical Systems methods on ELITech Clinical Systems Selectra analyzers.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Yung Chan

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

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